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STATE OF DELAWARE BOARD OF PHARMACY



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PUBLIC MEETING NOTICE: **BOARD OF PHARMACY**

DATE AND TIME: Wednesday, April 16, 2014 9:30 am

Conference Room A, 2nd Floor Cannon Building PLACE:

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: June 18, 2014

MEMBERS PRESENT

Joli Martini, R.Ph., PharmD, Professional Member, President Kimberly Robbins, R.Ph, Professional Member, Vice President Sandra Zaragoza, R.Ph, Professional Member Susan Esposito, R.Ph, Professional Member Tejal Patel, R.Ph, PharmD, Professional Member Bonnie Wallner, R.Ph, Professional Member Kenneth Sellers, Public Member Jay Galloway, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III

ALSO PRESENT

Suzanne Raab-Long Don Holst Jaime Frink Janis Levit Cheryl Heiks Sandra Robinson Russell Larson

Julie Miro Wenger Dot Hoa Abhi Shek De

CALL TO ORDER

Ms. Martini called the meeting to order at 9:31 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito, seconded by Ms. Zaragoza, to approve the meeting minutes for March 19, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Martini stated she attended the collaborative care meeting in March. She will be attending the NABP 2014 conference in May.

UNFINISHED BUSINESS

Complaint Status

- 13-03-11 Assigned to Hearing Officer
- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Forwarded to Office of Attorney General
- 13-19-11 Forwarded to Office of Attorney General
- 13-09-12 Assigned
- 13-01-13 Forwarded to Office of Attorney General
- 13-02-13 Assigned
- 13-03-13 Assigned
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Assigned
- 13-06-13 Forwarded to Office of Attorney General
- 13-07-13 Assigned
- 13-08-13 Assigned
- 13-09-13 Assigned
- 13-11-13 Forwarded to Office of Attorney General
- 13-13-13 Forwarded to Office of Attorney General
- 13-14-13 Assigned
- 13-15-13 Assigned
- 13-16-13 Assigned
- 13-17-13 Assigned
- 13-18-13 Assigned
- 13-19-13 Assigned
- 13-20-13 Assigned
- 13-21-13 Assigned
- 13-22-13 Assigned
- 13-23-13 Assigned
- 13-24-13 Assigned

A motion to amend the agenda was made by Mr. Sellers and seconded by Ms. Zaragoza to discuss SB118. The motion carried unanimously.

Ms. Martini stated that Ms. Julie Miro Wenger wanted to make the board aware of the passing of Substitute 1 SB118 in the senate on April 9, 2014. Ms. Wenger stated that Substitute 1 to SB 118 has been opposed by the large chain drug stores as well as the Medical Society and previously by the Delaware Board of Pharmacy. She felt it important to inform the board of the passing of this bill in the Senate so that the board would have the opportunity to address any concerns prior to the bill being presented to the House. Ms. Kelly, Deputy Attorney General advised the board of her concerns of voting on an issue without providing notice. She

expressed the right of the public to be properly informed so that opposing and supportive sides of the issue could be presented. A motion to schedule a board meeting on April 29, 2014 at 9:30 am to discuss SB118 was made by Ms. Zaragoza and seconded by Ms. Robbins. The motion carried unanimously.

Review of Consent Agreement - Neil Bavitz

Ms. Kelly presented the board with the signature page of the consent agreement that was approved during the March 19, 2014 meeting for the board members signatures. The agreement was passed to the board members for signature.

Review of Applications for Final Denial

None

Re-Review of Tabled Applications

None

NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Mr. Galloway, seconded by Ms. Esposito to ratify the approval of the Pharmacist applications of: Pharmacists: Safak Duru Paker-Leggs, Carrie F. Connahan, Mekbib M Belete, Heather M Sheridan Revel, Richard S Boahene, Carl D Tepper. Pharmacist Interns: James Young, Jack W Williams III. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Ms. Zaragoza to ratify the approval of the non-resident pharmacy applications: Express Scripts Pharmacy, Inc. Willingboro, NJ, Express Scripts Pharmacy, Inc. Las Vegas, NV, Express Scripts Pharmacy, Inc. Whitestown, IN, Eiris Health Services, Entracell Pharmacy, Norwood Pharmacy, LLC., Pinnacle Compounding, LLC., Express Scripts Pharmacy, Inc. Columbus, OH, Cardinal Health Pharmacy Services, LLC., Leehar Distributors Inc., Legacy Rx. LLC., Hill Country Apothecary, Coral Springs Specialty Pharmacy, Inc., GenRx, Innovo Specialty Compounding Solutions, Ken's Professional Compounding Pharmacy, Enclara Health, Gallos Pharmacy, LLC.- (Sterile Compounding). The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Ms. Zaragoza to ratify the approval of the wholesale distributor applications: Patterson Dental Supply, INO Therapeutics, TheraCom, LLC, ECR Pharmaceuticals Co., RGH Enterprises, Inc., Professional Hospital Supply, Inc., A-S Medication Solutions, Kroger Limited Partnership II, Vertical Pharmaceuticals, LLC., Kroger Limited Partnership I. The motion unanimously carried.

Medical Gas Dispensers

There were no applications to be ratified.

Retail Pharmacy Licensure Approval Ratification

A motion was made by Ms. Robbins, seconded by Ms. Zaragoza to ratify the approval of the retail pharmacy application: Equine Vet Supplies, LLC. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made to amend and add Pharmacist in Charge interview to the agenda to by Mr. Sellers, seconded by Ms. Patel. The motion unanimously carried.

Alfred M Gathura, he is employed by Rite-Aid Camden, DE. Mr. Gathura was not present at the meeting. He will be added to the next scheduled meeting agenda.

Consultant Pharmacist Interviews

None

Review of Consent Agreement

None

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Facility: Davis Drug, Inc. – Non Resident Pharmacy, a motion was made by Ms. Robbins, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Facility: TCS Labs, Inc. – Non Resident Pharmacy, a motion was made by Mr. Sellers, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

Facility: Vet Meds N More, Inc. – Non Resident Pharmacy, a motion was made by Ms. Zaragoza, seconded by Mr. Sellers, to table the application for more information. The motion unanimously carried.

Facility: LCRx, LLC. – Non Resident Pharmacy, a motion was made by Mr. Galloway, seconded by Ms.

Wallner, to table the application for more information. The motion unanimously carried.

Facility: MWI Veterinary Supply Co. – Wholesale Distributor, a motion was made by Mr. Galloway, seconded by Ms. Zaragoza, to approve the application. The motion unanimously carried.

Facility: INO Therapeutics, LLC. – Wholesale Distributor, a motion was made by Ms. Robbins, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

Pharmacist: Kalpesh C Patel – request to go from inactive to active, a motion was made by Ms. Wallner, seconded by Ms. Robbins, to approve the change to active status once the duty to report supplement and criminal history is received from Mr. Patel. The motion unanimously carried.

Pharmacist: Lisa Odenwelder, a motion was made by Mr. Galloway, seconded by Ms. Zaragoza to approve the application. The motion unanimously carried.

COMMITTEE REPORTS

Legislative - Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

Ms. Martini stated that SB118 would be a topic of discussion for the meeting scheduled for April 29, 2014.

Continuing Education — Joli Martini, Bonnie Wallner, and David Dryden:

No Report

Consumer Affairs - Ken Sellers and Jay Galloway:

No Report

Professional Liaisons – Kim Robbins and Sandra Zaragoza:

Ms. Zaragoza reported the events of the meeting held in April 2014. Ms. Martini read a report provided by Ms. Sandy Robinson.

Controlled Substance Liaisons - Joli Martini, Jay Galloway and David Dryden:

Mr. Dryden reminded the board of the upcoming meeting on April 23, 2014. He introduced Michelle McCreary the newly hired inspector for the board. Mr. Dryden and Ms. McCreary are providing copies of the new controlled substance regulations that went into effect on April, 11, 2014. An alert has also been sent to all practitioners' regarding the regulations.

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Howard Simon, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden reported that he had attended the FDA meeting held in Washington DC on March 20. 2014. He stated that Mr. Carmen Catizone spoke regarding office use. Mr. Catizone reiterated that "Office Use" is not permitted due to the FDA amendments to 503 (A) and 503 (B). He stated that per 503(A) requires a prescription to compound; 503(B) requires a facility to be established as an "outsourcing facility" in order to

compound beyond prescriptive limits. Mr. Dryden advised the Board that the processes for possible licensing of outsourcing facilities is an issue since states could either license the facility as a pharmacy; as an outsourcing facility; as both or as nothing. Mr. Dryden solicited the assistance of the Board's Deputy Attorney General Eileen Kelly to assist with the best way to license these types of facilities.

Pharmacy Technician Licensure Committee – Howard Simon, Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Sandy Esposito and David Dryden:

Ms. Robbins reported that "Draft" legislation should be available for review during the next meeting.

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Howard Simon, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden: Ms. Wallner and Mr. Wenger reported that "Draft" legislation has been distributed to members for review. It was also shared with the medical society for review. There were a few comments received regarding ratios and definition clarification.

BOARD CORRESPONDENCE

Wall Street Journal Article regarding: Walgreens Well Experience, handout provided.

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim

Mr. Dryden shared a request on behalf of Samantha Nettesheim requesting a letter of support for the Harold Rogers and NASCSA grants for the PMP. A motion was made by Ms. Esposito seconded by Ms. Zaragoza to provide a letter of support for each. The motion passed unanimously.

Mr. Dryden provided the board with an update on the PMP and the future of the project.

Mr. Dryden reminded the board of the NABP National conference May 20-21, 2014. Also, a Drug disposal is scheduled from 10am-2pm on April 26, 2014 at many locations across the state.

NEWSLETTER UPDATES

Newsletter has been completed. The next newsletter will include the new Controlled Substance rules and regulations that went into effect on April, 11, 2014.

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

Mr. Russell Larson addressed the board regarding his interpretation of Title 29 Chpt.100 §10002 and §10004(e) 2. He stated that the board could have placed a vote regarding SB118 based on the statue above. Ms. Kelly DAG for the board asked Mr. Larson if he was an attorney. He stated he was not. Ms. Kelly stated that she advised the board regarding her FOIA concerns with conducting a vote without providing adequate notice to the public.

Don Holst asked: if a patient that lives in Pennsylvania, visits a doctor in Delaware, has the prescription filled in Delaware, but requests it be mailed to their home in Pennsylvania is this allowed? The board stated that this is allowed understanding that the pharmacy shipping into Pennsylvania will have to follow Pennsylvania's statue for shipping to patients in Pennsylvania. Mr. Holst also shared his opposition for SB118.

NEXT SCHEDULED MEETING

The next meeting is scheduled for April 29, 2014 at 9:30 am., Conference Room A 2nd floor. This meeting was scheduled earlier in the meeting.

ADJOURNMENT

There being no other business before the board. A motion to adjourn was made by Mr. Sellers, seconded by Ms. Robbins. The motion unanimously carried at 11:15 am.

Respectfully submitted,

Christine Mast

Administrative Specialist III